Catheter Connections, Inc.
Donald Soloman
Sr.VP of Operations & Engineering/Chief Technology Officer
2455 E Parleys Way - Suite 150
Salt Lake City, Utah 84109

March 11, 2022

Re: K142399
Trade/Device Name: DualCap IV Pole Strips(Disinfectant Caps for Male Luers)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Donald Soloman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 19, 2014 and the correction letter dated March 6, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 6, 2019

Catheter Connections, Inc.
Donald Solomon Ph.D.
Sr.VP of Operations & Engineering/Chief Technology Officer
2455 E Parleys Way - Suite 150
Salt Lake City, Utah 84109

Re: K142399
Trade/Device Name: Dark Blue DualCap® for Male Luers
Regulatory Class: Unclassified
Product Code: QBP
Dated: August 19, 2014
Received: August 27, 2014

Dear Donald Solomon:

This letter corrects our substantially equivalent letter of November 19, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142399

Device Name
Catheter Connections' Dark Blue DualCap for Male Luers

Indications for Use *(Describe)*
When left in place for five (5) minutes, the Dark Blue DualCap disinfects male luer connectors; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

K142399

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(21 CFR 807.92)

for the Catheter Connections' Dark Blue DualCap® for Male Luers

SUBMITTER:

Catheter Connections, Inc.
2455 East Parley's Way, Suite 150
Salt Lake City, UT 84109

CONTACT:

Donald D. Solomon, Ph.D.
Telephone: (801) 209-1269
Fax: (888) 862-2693
Email: dsolomon@cathcomm.com

Date Prepared: August 7, 2014

SUBMISSION DEVICE:

Trade Name:	Dark Blue DualCap® for Male Luers
Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

PREDICATE DEVICE:

DualCap® for Male Luers (K123967):
(This predicate device has not been subject to a design-related recall)
(No reference devices were used in this submission)

Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

DEVICE DESCRIPTION:

The Dark Blue DualCap® is designed to fit securely on all ISO standard male luer connectors and provides effective disinfection of the male luer connector after five minutes of application. The cap contains 70% isopropyl alcohol. The product is intended for single-use and is provided sterile. This device is not made with natural rubber latex, is non-pyrogenic, preservative free and is not made with DEHP.

Additionally, Dark Blue DualCap® will be marketed for use as an accessory in procedure kits. When being used in procedural kits, the product will be shipped bulk sterile to the kitting manufacturer for incorporation into the procedure kits.

INTENDED USE:

The Dark Blue DualCap®, intended for use on male luer connectors, will disinfect and decontaminate male luer connectors and act as a barrier to contamination between uses.

The Dark Blue DualCap® will disinfect the connections within five (5) minutes after application and act as a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

INDICATIONS FOR USE:

When left in place for five (5) minutes the Dark Blue DualCap® disinfects male luer connectors; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

The difference in the Indications for Use for the submission device compared to the predicate device is a clarification that the Dark Blue DualCap® can be used on any male luer connector since male luers are dimensionally governed by an international standard (ISO) and are not device specific.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Disinfection of surfaces by exposure to 70% isopropyl alcohol (IPA) contained in a plastic cap while protecting the fluid pathway from disinfectant contamination is the general principle for both the submission and predicate devices. The submission and predicate devices are both based on the following technological elements:

- The devices are hermetically sealed and radiation sterilized
- They utilize an IPA reservoir
- They utilize an elastomeric tip to block the fluid pathway upon connection to a male luer
- There is an internal component which maintains the elastomeric tip noted above in contact with the orifice of the fluid pathway
- They have an ISO compliant female luer 6% taper dimensional feature to mate with male luer 6% taper feature
- They are mechanically secured via ISO compliant threads onto male luer connectors
- They disinfect and protect male luer connectors

There are no technological differences between the submission and the predicate device:

- The submission device is physically identical to the predicates device. They have the same technological characteristics:
    - Same design

- Same materials
- Same components
- Same method of manufacture
- Same plastic injection molds used to make the polypropylene Dark Blue caps
- Same method of operation
- Same sterilization method

- No change in the function/performance indication
- No change in patient population
- No change in clinical context

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation for the dark blue cap was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. The submission device and predicate devices are identical. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity
- Hemocompatibility
- Pyrogen.

Microbiological testing
Time Kill Studies were conducted for the evaluation of products for antimicrobial activity against selected organisms using an industry standard protocol for time-kill assays (ASTM E 2315-03, 2008). The product is challenged with the test organism(s) and then assayed at selected time points to determine antimicrobial efficacy on a wide range of microorganisms such as *Staphylococcus aureus, Pseudomonas aeruginosa, Streptococcus pyogenes*, antibiotic-resistant bacteria such as MRSA, VRE and yeasts such as (*Candida albicans* and *Candida krusei*. The study has shown a ≥ 4 log reduction in all cases.

Additional *in vitro* antimicrobial efficacy studies were completed on the Dark Blue DualCap® for Male Luers under worst case conditions and show a ≥ 4 log reduction in each test organism (*Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa*, and *Escherichia coli*).

Other performance tests
Physical tests were performed to ensure that Dark Blue DualCap® for Male Luers was compatible with typical male luer devices such as those found on IV administration sets and

syringes. Applicable testing using ISO 594-1 and ISO 594-2 was completed. The Dark Blue DualCap® for Male Luers passed all tests.

Testing was also completed to demonstrate that the Dark Blue DualCap® for Male Luers did not allow disinfectant to enter into the fluid path of the male luers.

CONCLUSION

The Submission Device is physically identical to the predicate device in terms of intended use, design, materials, operation, function, and sterilization method. All established acceptance criteria for performance testing for the predicate are identical to the Submission Device. This demonstrates that the Submission Device is safe and effective for its intended use, and based on FDA's 510(k) Decision-Making Flowchart is substantially equivalent to the Dark Blue cap of the Predicate Device (K123967).

DEPARTMENT OF
HEALTH & HUMAN SERVICES

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